

Applicants: Sharon Cohen-Vered et al.  
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Filed : January 14, 2004  
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#### **Remarks**

Claims 1-14, 16, 24-25, 27, 36-38, 47-48 and 52 were pending in the subject application. By this amendment, Applicants have canceled claims 38 and 48, amended claims 27, 36, 47 and 52, and withdrawn claims 14, 16, 27, 36-37 and 47.

Support for the amendments to claim 27 may be found, *inter alia*, on pages 21, line 25 to page 23, line 28 of the specification.

#### **Restriction Requirement**

In the June 1, 2006 Office Action, the Examiner required restriction of the invention under 35 U.S.C. §121 to one of the following allegedly independent and distinct inventions: Group I, comprising claims 1-13, 15, 24-26, 37, 48-52; Group II, comprising claim 14; Group III, comprising claims 16-23; and Group IV, comprising claims 27-47.

As a preliminary matter, Applicants contend that the separation of Groups III and IV is improper. Group IV merely claims the process of making a composition of Group I, where the composition is lyophilized. As such, Group IV should not be a restricted group but rather be together with Group III directed to a process of making the composition of Group I. To clarify this, Applicants have amended claim 27 and canceled claim 38 herein. Accordingly, claim 27, as amended, should be within Group III.

Applicants also point out that claims 15, 17-23, 26, 28-35, 39-46 and 49-51 were canceled in the Preliminary Amendment filed January 14, 2004 in order to reduce the filing fee. However, the Examiner has included these canceled claims in the restriction of the invention under 35 U.S.C. §121. As such, Applicants note the Examiner's indication of which Group each of the canceled claims belongs to, and Applicants reserve the right to add back into this

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application the cancelled dependent claims upon indication of allowable independent claims in the corresponding Groups.

In conclusion, for the purposes of responding to the requirement for restriction, Applicants elect from one of the following allegedly independent and distinct inventions: Group I, comprising pending claims 1-13, 24-25, 48 and 52; Group II, comprising pending claim 14; Group III, comprising pending claim 16; and Group IV, comprising pending claims 27, 36-37 and 47.

In response to the restriction requirement, Applicants elect, with traverse, claims 1-13, 24-25, 48 and 52, corresponding to **Group I**, drawn to a pharmaceutical composition. Applicants, however, traverse the restriction on the ground that 37 C.F.R. §1.141(b) in any event requires rejoinder of method of use claim 14, as well as the process of making claims 16, 27, 36-37 and 47, upon Applicants' election of product claims 1-13, 24-25, 48 and 52.

#### Election of Species

In the June 1, 2006 Office Action, the Examiner also required an election of species within the elected Group. Applicants hereby elect, with traverse, the species **SEQ ID NO: 6** for purposes of initial examination.

Applicants, however, respectfully submit that restriction to the species **SEQ ID NO: 6** is unduly limiting. At minimum, Applicants are entitled to the examination of the subgenus represented by **SEQ ID NO: 16**.

**SEQ ID NO: 16** represents a group of peptides based on the CDR1 region of the heavy chain of human 16/6Id mAb (see page 87, lines 13-15 of the specification) having a common core structure of amino

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acids. SEQ ID NO: 6 is a member of the group defined by SEQ ID NO: 16.

Because all members of the group defined by SEQ ID NO: 16 have amino acids in common, and are based on the CDR1 region of the heavy chains of human 16/6Id mAb, the search is straightforward. Accordingly, examination of claims 1-14, 16, 24-25, 27, 36-37, 47-48 and 52, all of which read on the elected species, can be performed without undue burden.

Furthermore, Applicants point out that the required election of a single, distinct peptide is contrary to M.P.E.P. §803.04, which provides that up to ten (10) independent nucleotide sequences shall be examined in a single application without restriction. In accordance with this provision, in the subject application Applicants respectfully request examination of the reasonable number of peptides represented by SEQ ID NO: 16.

Accordingly, Applicants respectfully request reconsideration of the election of species requirement.

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**FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

In accordance with their duty of disclosure under 37 C.F.R. §1.56, Applicants direct the Examiner's attention to the following references, which are listed on Form PTO-1449 (**Exhibit A**).

Pursuant to the Notice appearing in the August 5, 2003 Official Gazette, because this application was filed after June 30, 2003, copies of the U.S. Patents and U.S. Patent Application Publications listed herein, specifically Document 1, is not provided.

1. U.S. Patent No. 4,656,158, issued April 7, 1987 (Matsuo, et al.).

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b) before the mailing of a first Office Action on the merits. Thus, this Information Disclosure Statement should be entered and considered.

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**Summary**

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorneys invite the Examiner to telephone at the number provided below.

No fee, other than the enclosed \$120.00 fee for one-month extension, is deemed necessary in connection with the filing of this response. However, if any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
<i>Gary J. Gershik</i> John P. White Reg. No. 28,678 Gary J. Gershik Reg. No. 39,992	<i>7/27/06</i> Date

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